

### **REMARKS**

The Office Action of May 7, 2007, has been carefully reviewed and these remarks are responsive thereto. Reconsideration and allowance of the instant application are respectfully requested in view of the amendments and remarks presented in this response.

Claims 1-2, 4-8, 11-13, 15 and 25-38 are pending in this application. By this Amendment, no claims have been amended, added, cancelled, or withdrawn. Claims 1-2, 4-8, 11-13, 15 and 25-38 stand rejected.

#### **Claim Rejections Under 35 USC §102**

Claims 1, 2, 4, 27, 29, 31, 32, 34, 36, and 37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,879,017 to Vanderstraeten ("Vanderstraeten"). Applicants respectfully traverse this rejection.

#### **Claims 1, 2, and 4**

Claim 1 includes, among other features, "the matrix having a pore size of between about 150 to about 400  $\mu\text{m}$  and a porosity of between about 50% to about 60% by volume." Vanderstraeten does not disclose an implant having the recited pore size or porosity. The Office Action points to Col. 4, Lns. 36-42 of Vanderstraeten for disclosure of the claimed pore size. However, the cited portions of Vanderstraeten do not discuss pore size of the matrix material. Rather, the cited portions of Vanderstraeten relate to the particle size of a hydroxyapatite coating. Vanderstraeten does not discuss porosity or pore size of the matrix material.

Additionally, the Office Action points to Col. 2, Lns. 15-25 for disclosure of the claimed porosity. However, the cited portions of Vanderstraeten do not discuss pore size. Rather, the cited portions of Vanderstraeten relate to the volume fraction of carbon fibers that are contained in the disclosed composite. Again, Vanderstraeten does not discuss porosity or pore size of the matrix material.

Accordingly, Vanderstraeten does not disclose, teach, or suggest at least this element of claim 1, and cannot anticipate claim 1. For the same reasons, Vanderstraeten also cannot anticipate dependent claims 2, 4, and 27 depending from claim 1.

Dependent claim 2 also includes the features, "the natural bone structure substantially replaces the implant after the period of time." Vanderstraeten does not disclose, teach, or

suggest this additional element of claim 2. Vanderstraeten merely discloses “boney ingrowth” into the hydroxyapatite coating to fix the implant in position, and does not disclose ingrowth into the matrix or replacement of the matrix of the implant. Further, Vanderstraeten cannot be considered to implicitly disclose this element of claim 2 because the implant disclosed in Vanderstraeten is not otherwise identical to the claimed implant. For example, as described above, the implant disclosed in Vanderstraeten does not have the recited pore size or porosity. Additionally, the implant of Vanderstraeten contains 60% carbon fibers by volume (Col. 2, Ln. 23), and does not disclose that these carbon fibers will degrade or be resorbed or otherwise replaced by bone over time. Accordingly, one skilled in the art would not “reasonably be expected” to conclude, from the disclosure of Vanderstraeten, that the implant would be substantially replaced by natural bone structure over time. See M.P.E.P. § 2144.01. Thus, Vanderstraeten also does not disclose this element of claim 2, and cannot anticipate claim 2 for this additional reason.

#### **Claims 29, 31, and 32**

Claim 29 includes, among other features, “the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” As described above with respect to claim 1, Vanderstraeten does not discuss or disclose pore size or porosity of the disclosed prostheses. Accordingly, Vanderstraeten does not disclose at least this element of claim 29, and cannot anticipate claim 29. For the same reasons, Vanderstraeten also cannot anticipate dependent claims 31 and 32 depending from claim 29.

Claim 32 also includes the features, “the composition for enhancing the rate of bone growth both coats at least a portion of the structure and fills at least a portion of the pores of the structure.” Vanderstraeten does not disclose, teach, or suggest this additional element of claim 32. Even if Vanderstraeten is considered to disclose a composition for enhancing the rate of bone growth, Vanderstraeten does not disclose that such a composition “fills at least a portion of the pores” of the disclosed structure. As described above, Vanderstraeten does not disclose that the material of the implant is porous, and thus, Vanderstraeten also does not disclose that any pores are filled by a growth enhancing composition. Thus, Vanderstraeten also does not disclose this element of claim 32, and cannot anticipate claim 32 for this additional reason.

### **Claims 34, 36, and 37**

Claim 34 includes, among other features, “the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” As described above with respect to claim 1, Vanderstraeten does not discuss or disclose pore size or porosity of the disclosed prostheses. Accordingly, Vanderstraeten does not disclose at least this element of claim 34, and cannot anticipate claim 34. For the same reasons, Vanderstraeten also cannot anticipate dependent claims 36 and 37 depending from claim 34.

Claim 37 also includes the features, “the composition for enhancing the rate of bone growth both coats at least a portion of the structure and fills at least a portion of the pores of the structure.” This feature is similar to the feature discussed above with respect to claim 32. Thus, for the reasons discussed above with respect to claim 32, Vanderstraeten does not disclose, teach, or suggest this additional element of claim 37, and cannot anticipate claim 37 for this additional reason.

### **Claim Rejections Under 35 USC §103**

#### **Rejections of Claims 5, 12, and 26**

Claims 5, 12, and 26 were rejected under 35 U.S.C. §103(a) for being unpatentable over Vanderstraeten in view of U.S. Patent No. 4,645,503 to Lin et al. (“Lin”) and U.S. Patent No. 6,228,117 to DeBruijn et al. (“De Bruijn”). The cited references do not disclose, teach or suggest all the elements of claims 5, 12, and 26.

Claim 5 depends from claim 1 and includes, among other features, “the matrix having a pore size of between about 150 to about 400  $\mu\text{m}$  and a porosity of between about 50% to about 60% by volume.” Similarly, claim 12 depends from claim 11 and includes, among other features, “the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” Claim 26 depends from claim 25 and includes, among other features, “the biocompatible substrate has a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” As discussed above with respect to claims 1, 29, and 34, Vanderstraeten does not disclose a porous matrix material, and does not disclose the pore size or porosity recited in claims 5, 12, or 26. Neither Lin nor DeBruijn discloses the recited matrix material having the recited porosity or pore size, and the Office Action does not cite any such disclosure in Lin or DeBruijn.

Applicants further note that Lin merely discloses making modifications to control a single degradation rate (Col. 2, Lns. 46-57; Col. 5, Lns. 17-25), and does not disclose an implant having two portions with different degradation rates, as recited in claims 5, 12, and 26. Accordingly, the cited references do not disclose all the elements of claims 5, 12, and 26, and no prima facie case of obviousness has been established with respect to claims 5, 12, or 26.

#### **Rejections of Claims 6, 8, 30, and 35**

Claims 6, 8, 30, and 35 were rejected under 35 U.S.C. §103(a) for being unpatentable over Vanderstraeten in view of DeBruijn. The cited references do not disclose, teach or suggest all the elements of claims 6, 8, 30, and 35.

Claims 6 and 8 depend from claim 1 and include, among other features, “the matrix having a pore size of between about 150 to about 400  $\mu\text{m}$  and a porosity of between about 50% to about 60% by volume.” Similarly, claim 30 depends from claim 29 and includes, among other features, “the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” Claim 35 depends from claim 34 and includes, among other features, “the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” As discussed above with respect to claims 1, 29, and 34, Vanderstraeten does not disclose a porous matrix material, and does not disclose the pore size or porosity recited in claims 6, 8, 30, or 35. DeBruijn also does not disclose the recited matrix material having the recited porosity or pore size, and the Office Action does not cite any such disclosure in DeBruijn.

Additionally, the Office Action does not point out any disclosure in DeBruijn of a growth enhancing composition that includes a biocompatible polymer-ceramic composition. Applicants note that the polymer-ceramic composition disclosed at Col. 6, Lns. 25-26 of DeBruijn is part of the matrix composition, and is not disclosed for use as part of a growth enhancing composition. DeBruijn also does not suggest using the polymer-ceramic composition in combination with a calcium source to form a growth enhancing composition. Accordingly, the cited references do not disclose all the elements of claims 6, 8, 30, and 35, and no prima facie case of obviousness has been established with respect to claims 6, 8, 30, and 35.

### **Rejections of Claim 7**

Claim 7 was rejected under 35 U.S.C. §103(a) for being unpatentable over Vanderstraeten in view of DeBruijn and U.S. Patent No. 6,534,084 to Vyakarnam et al. (“Vyakarnam”). The cited references do not disclose, teach or suggest all the elements of claim 7.

Claim 7 depends from claim 1 and includes, among other features, “the matrix having a pore size of between about 150 to about 400  $\mu\text{m}$  and a porosity of between about 50% to about 60% by volume.” As discussed above with respect to claim 1, Vanderstraeten does not disclose a porous matrix material, and does not disclose the pore size or porosity recited in claim 7. The Office Action also does not cite any disclosure of such a porous material in Vyakarnam. A previous Office Action cited portions of Vyakarnam (Col. 5, Ln. 66 – Col. 6, Ln. 41) as disclosing a porous material. However, the previously cited portions of Vyakarnam are directed to a foam for repairing cartilage defects, and not for a load bearing bone implant. Vanderstraeten, which relates to bone implants, does not disclose or suggest a porous structure. Additionally, Vyakarnam does not disclose use of PBT or PEEK. Rather, for bone tissue repair, Vyakarnam discloses the use of caprolactone. (See, e.g., Col. 7, Lns. 24-50). Thus, the cited references do not disclose all the elements of claim 7, and no prima facie case of obviousness has been established with respect to claim 7.

Claim 7 also includes the features of claims 4 and 6. As discussed above, claims 4 and 6 contain features not disclosed by Vanderstraeten and/or DeBruijn. The Office Action does not identify these features in Vyakarnam. Thus, for these additional reasons, no prima facie case of obviousness has been established with respect to claim 7.

### **Rejections of Claims 11, 13, 15, 25, and 28**

Claims 11, 13, 15, 25, and 28 were rejected under 35 U.S.C. §103(a) for being unpatentable over Vanderstraeten in view of DeBruijn. The cited references do not disclose, teach or suggest all the elements of claims 11, 13, 15, 25, and 28.

Claim 11 includes, among other features, “the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ .” As discussed above with respect to claims 1, 29, and 34, Vanderstraeten does not disclose a porous matrix material, and does not disclose the pore size or porosity recited in claim 11. DeBruijn

also does not disclose the recited matrix material having the recited porosity or pore size, and the Office Action does not cite any such disclosure in DeBruijn. Accordingly, Vanderstraeten does not disclose at least this element of claim 11, and cannot anticipate claim 11. For the same reasons, Vanderstraeten also cannot anticipate dependent claims 13 and 15 depending from claim 11.

Claim 25 includes, among other features, "the biocompatible substrate has a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ ." As discussed above with respect to claims 1, 29, and 34, Vanderstraeten does not disclose a porous matrix material, and does not disclose the pore size or porosity recited in claim 25. DeBruijn also does not disclose the recited matrix material having the recited porosity or pore size, and the Office Action does not cite any such disclosure in DeBruijn. Accordingly, Vanderstraeten does not disclose at least this element of claim 25, and cannot anticipate claim 25. For the same reasons, Vanderstraeten also cannot anticipate dependent claim 28 depending from claim 25.

### **Rejections of Claims 33 and 38**

Claims 33 and 38 were rejected under 35 U.S.C. §103(a) for being unpatentable over Vanderstraeten in view of U.S. Patent No. 4,655,777 to Dunn et al ("Dunn"). The cited references do not disclose, teach or suggest all the elements of claims 33 and 38.

Claim 33 depends from claim 29 and includes, among other features, "the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ ." Claim 38 depends from claim 34 and includes, among other features, "the porous structure having a porosity between about 25% to about 70% by volume and a pore size between about 100 to about 2400  $\mu\text{m}$ ." As discussed above with respect to claims 1, 29, and 34, Vanderstraeten does not disclose a porous matrix material, and does not disclose the pore size or porosity recited in claims 33 or 38. Dunn also does not disclose the recited matrix material having the recited porosity or pore size, and the Office Action does not cite any such disclosure in Dunn. Accordingly, the cited references do not disclose all the elements of claims 33 and 38, and no prima facie case of obviousness has been established with respect to claims 33 and 38.

**Presentation is not a Printed Publication**

Applicants note the Examiner's statements regarding the presentation given by Dr. Vaidyanathan. Applicants further point out that the case law cited in Applicants' previous response is directly on point and supports the conclusion that Dr. Vaidyanathan's presentation did not constitute a printed publication. Additionally, Applicants submit that Applicant is not required to "positively verify that the information was not available publicly for a time to allow the presentation's information to be printed and disseminated and/or displayed." The case law identifies no such burden for Applicant to meet, but rather, identifies several factors to consider. The circumstances of Dr. Vaidyanathan's presentation were very similar to those in *Regents of the University of California v. Howmedica, Inc.*, 530 F.Supp. 846, 860, 210 U.S.P.Q. 727, 738-39 (D. N.J. 1981), in which the presentation at issue was not considered to be a printed publication. Thus, Dr. Vaidyanathan's presentation did not constitute a printed publication under § 102(b).

**CONCLUSION**

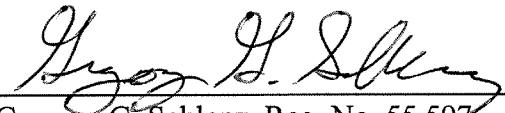
In view of the above amendments and remarks, prompt reconsideration and full allowance of claims 1-2, 4-8, 11-13, 15 and 25-38 in the subject application are respectfully requested. All rejections have been addressed. Applicants respectfully submit that the instant application is in condition for allowance and respectfully solicit prompt notification of the same.

The Commissioner is authorized to debit or credit our Deposit Account No. 19-0733 for any fees due in connection with the filing of this response.

The Examiner is invited to contact the undersigned at the number set forth below should the Examiner believe that a further conversation would be useful in the prosecution of this case.

Respectfully submitted,

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By:   
Gregory G. Schlenz, Reg. No. 55,597  
Banner & Witcoff, Ltd.  
10 South Wacker Drive  
Suite 3000  
Chicago, IL 60606  
Telephone: 312-463-5000  
Facsimile: 312-463-5001

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